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PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Artcle 36 and Rule 70)

Applicant's or agent's file reference 02-66191	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. **PCT/KR2003/002242**	International filing date *(day/month/year)* **23 OCTOBER 2003 (23.10.2003)**	Priority date *(day/month/year)* 29 OCTOBER 2002 (29.10.2002)

International Patent Classification (IPC) or national classification and IPC

IPC7 A61L 15/14

Applicant

BIOPOL CO., LTD. et al

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   [X] This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 1 sheets.

3. This report contains indications relating to the following items:

   - I [X] Basis of the report
   - II [ ] Priority
   - III [ ] Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV [ ] Lack of unity of invention
   - V [X] Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI [ ] Certain documents cited
   - VII [X] Certain defects in the international application
   - VIII [ ] Certain observations on the international application

Date of submission of the demamd	Date of completion of this report
28 MAY 2004 (28.05.2004)	29 JANUARY 2005 (29.01.2005)

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International aplication No.
PCT/KR2003/002242

I. Basis of the report

1. With regard to the elements of the international application:*

- [ ] the international application as originally filed
- [ ] the description:
  pages _____ , as originally filed
  pages _____ , filed with the demand
  pages _____ , filed with the letter of _____
- [X] the claims:
  pages _____ , as originally filed
  pages 20 , as amended (together with any statment) under Article 19
  pages _____ , filed with the demand
  pages _____ , filed with the letter of _____
- [ ] the drawings:
  pages _____ , as originally filed
  pages _____ , filed with the demand
  pages _____ , filed with the letter of _____
- [ ] the sequence listing part of the description:
  pages _____ , as originally filed
  pages _____ , filed with the demand
  pages _____ , filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language English which is

- [ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- [X] the language of publication of the international application(under Rule 48.3(b)).
- [ ] the language of the translation furnished for the purposes of international preliminary examination(under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide** and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- [ ] contained inthe international application in written form.
- [ ] filed together with the international application in computer readable form.
- [ ] furnished subsequently to this Authority in written form.
- [ ] furnished subsequently to this Authority in computer readable form
- [ ] The statement that the subsequently furnished written sequence listing does not go beyond the disc losure in the international applicationas as filed has been furinshed.
- [ ] The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. [X] The amendments have resulted in the cancellation of:
   - [ ] the description, pages _____
   - [X] the claims, Nos. 2
   - [ ] the drawings, sheets _____

5. [ ] This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box(Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed." and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item I and annexed to this report.*

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1 & 3	YES
	Claims	none	NO
Inventive step (IS)	Claims	1 & 3	YES
	Claims	none	NO
Industrial applicability (IA)	Claims	1 & 3	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Reference is made to the following documents from the International Search Report (ISR).

D1: US 2002/0062097 A

D2: KR 340981 B

D3: KR 2002-46619 A

Claim 2 was cancelled in the amendment submitted on 09. Apr. 2004.

1. Novelty

The object of the present invention is to provide a hydrophilic polyurethane foam dressing for a wound filler (claim 1), which is applicable to a deep wound oozing a large amount of exudate having high liquid permeability as well as high water vapor transmission, and a method (claim 3) therefor.

The technical solution set out by the present invention is to provide a polyurethane foam dressing composed of a plurality of open cells and pores, wherein the foam dressing has a density of 0.1~0.32 g/cm3, the average diameter of said open cells is 80~400 microns, and the average diameter of said pores is 30~80 microns. It is noted in the descriptions(page 6 lines 1~4) that the pores are formed on the surface of walls of the open cells and that a ratio of the open cells in the foam dressing is 50 to 90%.

D1 is considered to represent the most relevant state of the art for the subject matter of present invention with respect to providing an open-celled polyurethane foam. The cells of an average diameter of less than 70 microns have openings between the cells (corresponding to pores of the present invention) with an average diameter of less than 40 microns. Therefore, as described in the D1 (page 1 [0010]), such foams have high water vapor transmission and low liquid permeability as a resulting effect from the construction. That makes D1 different from the present invention.

- continued in Supplemental Box

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VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

Rule 5.1(a)(ii) requires that the description indicate the background art which, as far as known to the applicant, can be regarded as useful for the understanding, searching and examination of the invention, and preferably, cite the documents reflecting such art. It is considered that this rule has not been satisfied in the following reasons: (a) nevertheless D1 appears to be the most relevant prior art of the present invention, it has not been mentioned in the international application. (b) it would be appropriate to include a comprehensive discussion of the relevant background art in the present application to differentiate the prior art from the present invention.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of:

Box V.

D2 & D3 disclose a method for preparing a open-celled polyurethane foam dressing. However, the methods include a step forming a thin film layer, which have pores in itself but not in the open cells, on one surface(D3) or on both surfaces(D2) of the foam dressing. The resulting open cells disclosed in D2 & D3 do not contain pores in themselves. Therefore, D2 & D3 are different from the subject matter of claim 3.

There is no document disclosing such a technical solution presented by claims 1 & 3 of the present invention. Accordingly, claims 1 & 3 appear to be novel fulfilling the criteria set forth in Article 33(2) PCT.

2. Inventive step
The object of D1 is different from that of the present invention in that D1 is to provide a foam dressing, which has low liquid permeability for use as a bandage backing materials, whereas the problem posed by the present invention is to provide a foam dressing that has high liquid permeability and absorbency for absorbing a large amount of exudate from the oozing wound. There is no suggestion in any of the available documents, which would lead to the technical feature of the present invention. No motivation is found either in prior arts that one skilled in the art would consider adopting the sizes of the open cells and pores set out by the present invention for the polyurethane foam dressing. The special effect that comes with the construction of the present invention is recognized to be unforeseen from prior arts. Therefore, claims 1 & 3 are believed to involve an inventive step fulfilling the requirements set forth in Article 33(3) PCT.

3. Industrial applicability
The object of the present invention is to provide a polyurethane foam dressing, which is industrially applicable. Consequently, claims 1 & 3 meet the requirements of Article 33(4) PCT.

Claims

1. (Amended) A hydrophilic polyurethane foam dressing composed of a plurality of open cells and pores, characterized in that said dressing is a filling type of foam dressing which is filled into the deep wound and then used as a wound filler and has a density of 0.1 to 0.32 g/cm^3, the average diameter of said open cells is 80 to 400㎛ and the average diameter of said pores is 30 to 80㎛.

2. (Deleted)

3. (Amended) A method of manufacturing a hydrophilic polyurethane foam dressing composed of a plurality of open cells and pores, including:

mixing and agitating 40 to 75 wt% polyurethane prepolymer, 15 to 45 wt% foaming agent, 5 to 35 wt% crosslinking agent, and 0.5 to 15 wt% additive containing a surfactant, a moisturizing agent, and a pigment;

injecting a resulting mixture into a mold; and

foaming the resulting mixture in the mold thereby having a density of 0.1 to 0.32 g/cm^3, the average diameter of said open cells being 80 to 400㎛ and the average diameter of said pores being 30 to 80㎛.